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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,035	BIGNON ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 4-8 12-18, drawn to a liquid pharmaceutical formulation comprising an Interleukin and capable of forming a gelled deposit *in vivo*.

Group II, claims 3-8, 12-15, 17, and 18, drawn to a liquid pharmaceutical formulation and capable of forming a gelled deposit *in vitro*.

Group III, claim 27, as drawn to claim 1, drawn to a method of making drugs for administration.

Group IV, claim 27, as drawn to claim 3, drawn to a method of making drugs for administration.

Group V, claims 28 and 29, as drawn to claim 1, drawn to a derived product comprising submicronic particles.

Group VI, claims 28 and 29, as drawn to claim 3, drawn to a derived product comprising submicronic particles.

Group VII, claims 30 and 31, as drawn to claim 1, drawn to a method of preparing a formulation with a colloidal suspension of nanoparticles.

Group VIII, claims 30 and 31, as drawn to claim 3, drawn to a method of preparing a formulation with a colloidal suspension of nanoparticles.

Group IX, claim 32, as drawn to claim 1, drawn to a method of preparing a formulation using a powder.

Group X, claim 32, as drawn to claim 3, drawn to a method of preparing a formulation using a powder.

Group XI, claim 33, as drawn to claim 1, drawn to a method of preparing a formulation by resuspending a powder produced by drying a liquid formulation.

Group XII, claim 33, as drawn to claim 3, drawn to a method of preparing a formulation by resuspending a powder produced by drying a liquid formulation.

Group XIII, claim 34, as drawn to claim 1, drawn to a method of preparing a powder by drying a formulation.

Group XIV, claim 34, as drawn to claim 3, drawn to a method of preparing a powder by drying a formulation.

2. Claims 9-11 and 19-26 cannot be grouped because they are multiple dependent claims that are dependent on multiple dependent claims or are dependent on dependent claims, which in turn are dependent on multiple dependent claims (see MPEP 608.01(n)).

3. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: claim 1 lacks novelty as being anticipated by Huille et al., US Patent 5,904,936 (18 May 1999). The '936 patent teaches liquid pharmaceutical compositions comprising non-hollow particles based on polyamino acids for the delivery of active principles wherein the particles that are obtained by contacting polyamino acids with an aqueous solution, wherein the polyaminoacids are linear with alpha-peptide linkages, comprising at least two types of recurring amino acids which are identical or different from one another, selected from the group consisting of a hydrophobic neutral amino acid (AAN), and an amino acid having an ionizable side chain (AAI), at least a portion of the AAI amino acid being in ionized form, having a weight average molar mass MW of not less than 4,000 D, are non-water soluble at acid pH or at a pH between 3 and 12 and have an average size between 0.01 μm and 0.5μm; further comprising at least one active principle; wherein the active principle is medicinal and is an interleukin (claims 1, 2, 7, and 12 of the '936 patent). See also, column 5, lines 17-28, teaching the sustained release of the composition and the use of the composition as a vaccine. Because the '936 patent anticipates claim 1, the remaining claims lack the same or corresponding special technical feature and restriction is required under lack of unity. See also 37 CFR 1.475 and MPEP 1850. It is also noted that claims 4, 5, 6, 27, 28, 30, 32, 33, and 34 are multiple dependent claims.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Formulas: I, II, III, IV

The formulas I, II, III, and IV are structurally distinct one from the other.

Applicant is required, in reply to this action, to elect **a single species** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Examiner, Art Unit 1647